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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,235	09/25/2006	Stephen Robert Wedge	056291-5302	1868
9629 7590 07/14/2009 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER PURDY, KYLE A	
			ART UNIT 1611	PAPER NUMBER
			MAIL DATE 07/14/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,235	<b>Applicant(s)</b> WEDGE, STEPHEN ROBERT	
	<b>Examiner</b> Kyle Purdy	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-24, 27, 28 and 31-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-24, 27, 28 and 31-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/03/2009 (1 page)</u> .                                     | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

1. The Examiner acknowledges receipt of the amendments filed on 04/03/2009 wherein claims 21-24, 27, 28 and 31-34 have been amended and claims 29 and 30 have been cancelled.
2. Claims 21-24, 27, 28 and 31-34 are presented for examination on the merits. The following rejections are made.

### ***Response to Applicants' Arguments***

3. Applicants arguments filed 04/03/2009 regarding the rejection of claims 21-24, 27 and 28 made by the Examiner under 35 USC 103(a) over Lee (US 2002/0002162) in view of Hilberg et al. (WO 2004/096224) have been fully considered and they are found persuasive. This rejection has been overcome because Hilberg does not qualify as a prior art reference.
4. Applicants arguments filed 04/03/2009 regarding the rejection of claims 29-34 made by the Examiner under 35 USC 103(a) over Lee in view of Hilberg in further view of Lane et al. (US 2004/0147541) have been fully considered and they are found persuasive. This rejection has been overcome because Hilberg does not qualify as a prior art reference. It's noted that claims 29 and 30 have been cancelled.
5. Applicants arguments filed 04/03/2009 regarding the rejection of claims 29 and 30 made by the Examiner under nonstatutory obviousness type double patenting have been fully considered and they are not found persuasive. This rejection has been overcome by cancellation of the claims. It's noted that the rejection over copending application 10/563440 is also withdrawn.

6. Applicants arguments filed 04/03/2009 regarding the rejection of claims 21-24, 27, 28 and 31-34 made by the Examiner under nonstatutory obviousness type double patenting have been fully considered but they are not found persuasive.

7. The rejection of claim 21-24, 27, 28 and 31-34 made by the examiner under nonstatutory obviousness type double patenting is **MAINTAINED** for the reasons of record in the office action mailed on 10/03/2008.

8. In regards to the double patenting rejection rejection, Applicant asserts the following:

A) No claims have been allowed in any case, thus the rejection should be withdrawn.

9. In response to A, this is not found persuasive. The rejection is provisional, as was stated in the previous office action meaning that the rejection was made knowing that claims involved in the rejection have not been allowed. Applicants argument is not persuasive.

**Maintained Rejections, of Record**  
***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 21-24 and 27-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/563439; 10563,440; 10/594,233; 10/594,234; 11,663,912 in view of Lee (US Pub No. 2002/0002162; Pub.Date Jan.3,2002.) The limitation of the claims in the instant application is drawn to AZD2171 combined with a platinum anti-tumor agent. The limitation of the claims of application 10/563439 is drawn to AZD2171 and ZD1839, which is an anti-tumor agent. Lee '162, teaches therapies for treatment of cancer, that further, teach a synergistic method for the treatment of cancer in a mammalian specie[0002,0011] which comprises a vascular endothelial growth factor receptor tyrosine kinase inhibitor, ZD6474 [0082], (Also a anti-tumor agent) in conjunction with carboplatin [0079], cisplatin and oxaliplatin [Table 1](platinum anti0tumor agtents) for the treatment of breast, pancreas, bladder colon lung, skin colorectal, non-small cell lung cancer and mesothelioma.[0059-0067]. Lee also teaches of radiation therapy that includes but is not limited to x-rays or gamma rays [0068], that is usually given at the same time as the cancer treating method discussed above. The platinum anti tumor agents (carboplatin, cisplatin, and oxaliplatin) used in the method of Lee '162 can also be added to the VEGF tyrosine kinase inhibitor (AZD2171) of copending Application No. 10/563439. This would be obvious to do so to provide a further cytotoxic agents. Copending applications: 10563,440; 10/594,233; 10/594,234; 11,663,912 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting because their claims can be modified by Lee for the same reasons stated above.

11. This is a provisional obviousness-type double patenting rejection.

**New Rejections**  
***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**14. Claims 21, 23, 24, 27, 28 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes et al. (WO 00/47212; published 08/17/2000).**

15. Stokes is directed to quinazoline derivatives as angiogenesis inhibitors. Stokes teaches that the instantly claimed compound AZD2171 (4-(4-fluoro-2-methylindol-5-yl)oxy)-6-methoxy-7-(3-(pyrrolidin-1-yl)propoxy)quinazoline (see page 57, line 31). The compound may be administered as the compound itself or in the form of a salt (see abstract). The method of treating angiogenesis with the compound of note as well as simultaneously administering radiotherapy and antineoplastic agents such as platinum derivatives like cisplatin and carboplatin (see page 85). It's taught that the radiotherapy and antineoplastic agents may be administered simultaneously, sequentially or separately from administration of the quinazoline derivative (see

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page 85, lines 1-5). The types of cancers treated by the compounds of Stokes include Kaposi's sarcoma as well as solid tumors such as colorectal and lung cancer (see page 86, lines 11-23).

16. Stokes fails to specifically teach using said compound in a method of treating cancer.

17. Regardless, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Stokes with a reasonable expectation for success in arriving at a method of treating cancer in a method of administering AZD2171 before after or simultaneously with a platinum anti-tumor agent and radiotherapy. Although stoke fails to specifically use the instantly claimed compound in a method of cancer treatment, any person of ordinary skill could have readily identified said compound for use in a method with a reasonable expectation for success in treating the condition. The reference teaches that AZD2171 is a more preferred compound for use in such treatments. Thus, it would not have been innovative to pick a compound that had been suggested for cancer treatment as the currently claimed method does because such method would have been a product of ordinary skill and common sense as any ordinary person would have been capable of n reading and utilizing the information presented by Stokes. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

**18. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes et al. (WO 00/47212; published 08/17/2000) as applied to claims 21, 23, 24, 27, 28 and 31-33 above, and further in view of Seibert et al. (US 5972986; published 10/26/1999).**

19. Stokes fails to teach oxalipatin as being a platinum-based antitumor agent.

20. Saibert cures this deficiency. Saibert teaches a variety of antineoplastic agents including cisplatin, carboplatin, as well as oxaliplatin (see column 13, lines 15-30).

21. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Stokes and Seibert with a reasonable expectation for success in arriving at a method of treating cancer wherein the platinum antitumor agent is oxaliplatin. One would have been motivated to use oxaliplatin in the method of treating cancer taught by Stokes with a reasonable expectation that the use of oxaliplatin would reduce the size of the cancer. Its use is especially obvious in view of Stokes specifically calling for use of platinum based antitumor agents. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

**22. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stokes et al. (WO 00/47212; published 08/17/2000) as applied to claims 21, 23, 24, 27, 28 and 31-33 above, and further in view of Oncology channel (<http://www.oncologychannel.com/lungcancer/types.shtml>, .pdf provided; published 08/24/1999).**

23. Stokes fails to specify the lung cancer as being non-small cell lung cancer (or large cell lung cancer)

24. Oncology channel teaches a variety of different lung cell types. Of those listed, non-small cell lung cancer is disclosed.



25. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Stokes and Oncology channel with a reasonable expectation for success in arriving at a method of treating cancer wherein the lung cancer is non-small cell lung cancer. Stokes teaches that lung cancer may be treated using their compounds. While Stokes does not specify non-small cell lung cancer, its selection from the various types of lung cancer would not have been difficult given that lung cancers exist as two groups: small cell and non-small cell. Any person of ordinary skill would have been capable of picking one of the two (i.e. non-small cell) for treatment with the method of Stokes with a reasonable expectation in the cancer being treated. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

### ***Conclusion***

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/  
Examiner, Art Unit 1611  
July 13, 2009*

*/David J Blanchard/  
Primary Examiner, Art Unit 1643*